IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Pepinsky et al.

Confirmation No.: 4023

Application No.: 10/802,540

Group Art Unit: 1647

Filing Date: March 16, 2004

Examiner: Fozia M. Hamud

Title: Polymer Conjugates of Interferon Beta-1A and Uses

DECLARATION BY DARREN P. BAKER PURSUANT TO 37 CFR §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam or Sir:

I, Darren P. Baker, do hereby declare and say under 37 CFR §1.132 the following:

1. I received a Ph.D. in the field of Biochemistry from The University of Glasgow, Scotland, UK in 1990 and a B.Sc. in the field of Microbiology from The University College of Swansea, Wales, UK in 1986.

2. I worked in several areas of biochemistry from 1983 to the present and a current member of the International Society for Interferon and Cytokine Research. I have reviewed manuscripts for the Journal of General Microbiology, Journal of Molecular Biology, Proceedings of the National Academy of Sciences USA, and Biochemistry.

3. I am a Principle Scientist in the Department of Drug Discovery at Biogen Idec, Inc., Cambridge, MA. I manage and direct Biogen's research related to interferon-beta including the development of potential new routes of administration for interferon-beta compositions.

4. I am an author on 43 peer-reviewed, scientific papers. Specifically in the area of interferon biochemistry, I am the author of 14 peer-reviewed, scientific papers.

5. I am familiar with the subject matter of this patent application and the recent comments by the Examiner regarding this application in the office action dated May 25, 2007.

6. I am familiar with the prior art references cited by the Examiner. More specifically, I am familiar with Mark et al., WO 8302461; Katre, et al., US 4,766,106; and Capon US 5,116,964;

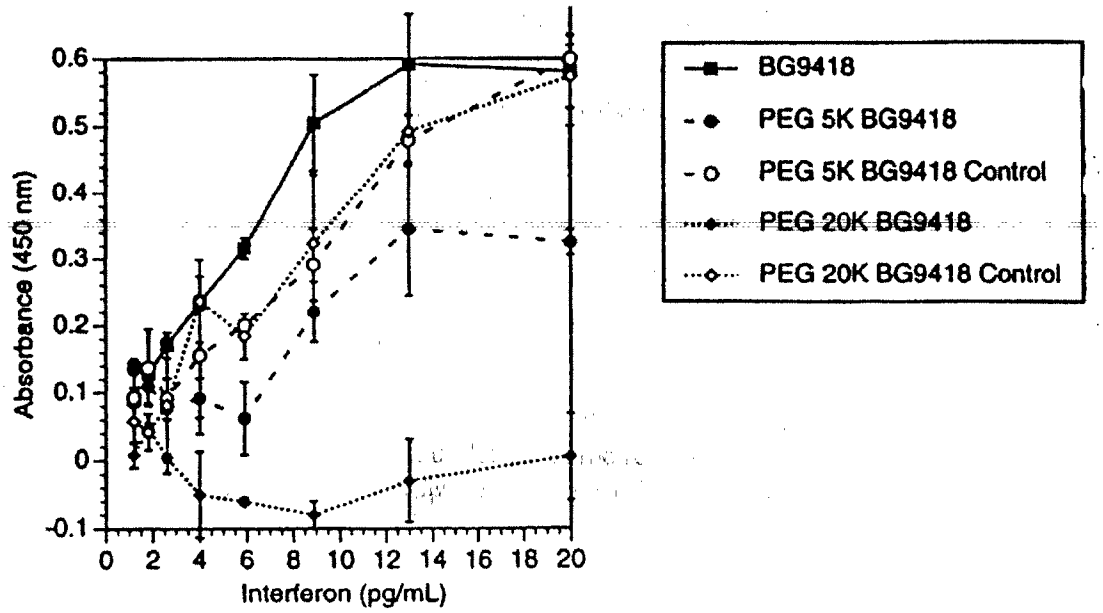
7. I have reviewed and understand that the enclosed studies (shown below) demonstrate unexpected and advantageous properties of the compositions according to the present invention over the prior art cited by the Examiner.

8. In January 2003, I learned of these results from the studies which were designed and conducted by my Biogen colleagues, Susan Goelz, Margot Brickelmaier, and a Shearwater Corporation collaborator, Mike Roberts. On September 14, 2005, I presented these results to Biogen's senior management in a Technical and Historical Review entitled "PEGylated IFN-β-1a."

9. The studies were started on 07/22/96 and finished on 09/20/96 in Cambridge, MA at Biogen's research facilities.

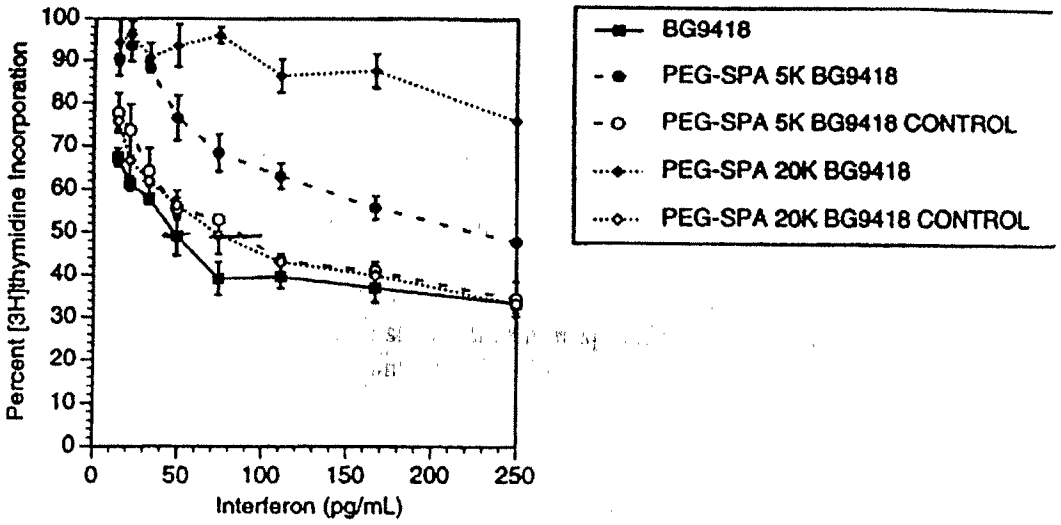
10. Figure 1 shows the effect of non-specific PEGylation with 5 kDa and 20 kDa PEG-SPA on the antiviral activity (viral replication) of human interferon-beta-1a (BG9418). The antiviral activity of BG9418 modified with either 5 kDa PEG-SPA or 20 kDa PEG-SPA, and their respective controls in which the protein was subjected to the same reaction conditions in the absence of PEG-SPA, is shown. The antiviral activity of untreated BG9418 is also shown. The data shows that non-specific modification of BG9418 with 5 kDa PEG-SPA results in loss of antiviral activity, and that the magnitude of the loss was greater than following incubation under the same reaction conditions in the absence of 5 kDa PEG-SPA. The data also show that non-specific modification of BG9418 with 20 kDa PEG-SPA results in the loss of almost all of the antiviral activity, a loss that was significantly greater than observed for the protein incubated under the same reaction conditions in the absence of 20 kDa PEG-SPA.

Figure 1. Antiviral activity of 5 kDa and 20 kDa PEG-SPA-modified IFN-β-1a



11. Figure 2 demonstrates the effect of non-specific PEGylation with 5 kDa and 20 kDa PEG-SPA on the antiproliferative activity of human interferon-beta-1a (BG9418). The antiproliferative activity of BG9418 modified with either 5 kDa PEG-SPA or 20 kDa PEG-SPA, and their respective controls in which the protein was subjected to the same reaction conditions in the absence of PEG-SPA, is shown. The antiproliferative activity of untreated BG9418 is also shown. The data shows that non-specific modification of BG9418 with 5 kDa PEG-SPA results in loss of antiproliferative activity, and that the magnitude of the loss was greater than following incubation under the same reaction conditions in the absence of 5 kDa PEG-SPA. The data also show that non-specific modification of BG9418 with 20 kDa PEG-SPA results in the loss of almost all of the antiproliferative activity, a loss that was significantly greater than observed for the protein incubated under the same reaction conditions in the absence of 20 kDa PEG-SPA.

Figure 2. Antiproliferative activity of 5 kDa and 20 kDa PEG-SPA-modified IFN-β-1a



I, Darren P. Baker further declare that all statements made herein are true to the best of my knowledge, or if made upon information and belief, are believed to be true. This Declaration is made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 US §1001, and may jeopardize the validity of the subject patent application or any patent issuing thereon.

Respectfully submitted,

11/21/07
Date

Darren P. Baker

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